Suggested Format for Residue Chemistry Study Reports

Processed Food and Feed

OPPTS 860.1520

The purpose of this document is to suggest the format for final reports (right column) and to provide instructions for creation of Adobe PDF electronic submission documents (left column). The format is modeled after the NAFTA Data Evaluation Record template that will be used by OPP's and PMRA's scientists when this type of study is reviewed. The format is in outline form. The study report will include text and standard tables (detailed below).

Regarding PDF, both 'bookmarks' and 'links' are referenced. Bookmarks and links are similar in function in that both provide the reader with a way to move efficiently through a document as well as across documents. Bookmarks are a type of link that appear in the navigation pane on the left side of the PDF Reader user screen. Links appear within the body of a document as blue text. They permit the reader to jump to other locations with related information in the same document or other electronic documents. Tables should be imported into the PDF document from their native formats. See OPP's detailed technical specifications for creating PDF for details.

Residue Chemistry Study Reports – PROCESSED FOOD AND FEED	
Instructions to create PDF	**Document Format**
Create Bookmarks for each item in document format column.	• Study Title Page. • Statement of Data Confidentiality *No confidentiality claims can be made for electronically submitted studies at this time.* • GLP Statement. • QA Statement. • Table of Contents.
Create links in summary to related text and tables in body of study report or appendices.	• Executive Summary. - Summary of Background Information & Experimental Design. - Summary of Results.
Create links to related tables.	• Background Information and Experimental Design. - Background Information – See Tables 1 and 2. - Experimental Design – See Table 3. - Analytical Methodology. • Results and Discussion – See Tables 4 - 6.

Executive Summary:

Identify the chemical name, %a.i., formulation type, crops, rate of applications, and The fractions that the RAC samples were processed into. Describe the analytical method that was used to analyze residues in the RAC and processed matrices. Also indicate whether or not storage stability has been demonstrated for the samples in the study. Include a comparison of the residues in the RAC with those in each processed fraction and concentration factors and whether not the concentration factors conformed with the theoretical concentration factors.

Study/Waiver Acceptability/Deficiencies/Clarifications:

List any scientific deficiencies or clarifications that are needed.

Background Information:

Give background information on the active ingredient, its mode of action, and the purpose of the end-use product.

Table 1 – Test Compound Nomenclature.

Compound	Chemical Structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/EP	

Table 2 – Physicochemical Properties.

Parameter	Value	Reference
Melting point/range		
pH		
Density		
Water solubility (__°C)		
Solvent solubility (mg/L at __°C)		
Vapor pressure at __°C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient Log (K_{ow})		
UV/visible absorption spectrum		

Experimental Design:

Application and Crop Information

Table 3 – Commodity, Application, and Harvesting Information.

Location (City, state)	Year	End-use product	Application						Tank mix adjuvants	Harvest procedures[1]
			Timing	Rate, lb a.i./A (kg a.i./ha)	Retreatment interval (days)	Treat. No.	Method	Total Rate lb a.i./A (kg a.i./ha)		

[1]Only applicable for cotton commodities

Processing Procedures

FIGURE 1. Processing Flowchart for [RAC].

Insert flowchart figure(s) that describe the steps taken to produce the processed commodities.

Analytical Methodology

Describe the principle of the analytical method including sample preparation and instrumentation used in determining the residues. State LOD and LOQ.

Results and Discussion:

Reference tables in the relevant part of the discussion.

Comment on the analytical method's suitability, providing information on the method validation (spiking levels, range of recoveries, average recovery and standard deviation), detector linearity, LOD and LOQ. Provide confirmation that the chromatograms of control samples of various crop matrices are free from interferences and/or discuss any apparent residues in control samples. The discussion should include a comparison to typical commercial practices and the suitability of the analytical method. Compare the empirical processing factors to theoretical processing factors. Discuss whether or not the storage stability study supports the storage durations/conditions of samples in the processing study. Include any pertinent information on corrections to residues due to in-storage dissipation.

Table 4 – Summary of Concurrent Recoveries of [*chemical*] from [*matrix*].

Matrix	Analyte	Spike level (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev.

Table 5 – Summary of Storage Conditions.

Matrix (RAC or Extract)	Storage temp. (°C)	Actual storage duration (days or months)	Limit of demonstrated storage stability (days or months)

Table 6 – Residue Data from [*RAC*] Processing Study with [*chemical*].

RAC	Processed Commodity	Total Rate lb a.i./A (kg a.i./ha)	PHI (days)	Residues (ppm)	Processing Factor